1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

November 26, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0456 Determining Hospital Procedures for Opened-But Unused, Single-Use Medical Devices

Dear Sir or Madam:

AdvaMed respectfully submits these comments to the Food and Drug Administration in response to your notice requesting comments about current practices with respect to opened-but-unused, single-use medical devices defined in the notice as "single-use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but not used on a patient, that is, they have not been in contact with blood or bodily fluids."

AdvaMed, the Advanced Medical Technology Association, represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems, including manufacturers of single-use medical devices. Our members produce nearly 90 percent of the $68 billion in health care technology products consumed yearly in the United States and nearly 50 percent of the $159 billion purchased around the world annually.

AdvaMed is providing general comments because the three specific topics listed for comment in the Notice[1] request information that is typically known to hospitals rather than original equipment manufacturers (OEMs).

---

[1] Whether or not hospitals have a written policy or procedure for handling sterile, single-use medical devices that are opened, for whatever reason, but are unused; (2) how hospitals determine if a single-use medical device that has been opened-but-unused is contaminated; and (3) what types of single-use medical devices are re-sterilized because they are opened-but-unused."

02N-0456

C4

AdvaMed agrees with FDA's decision to regulate opened-but-unused, single-use devices separately from reprocessed single-use devices that are reprocessed after exposure to contaminants from one or more patients, and are subject to fatigue from one or more uses. Important safety and effectiveness concerns are, nevertheless, presented by the re-sterilization of some devices even before the first use. For example, some single-use devices are designed for radiation sterilization and cannot tolerate the temperature or humidity stresses introduced through ethylene oxide (EO) or other sterilization processes. Issues also arise when the device materials or device mechanics are capable of being compromised by exposure to normal environmental conditions, or to repeated sterilization cycles. In these instances, original device packaging and expiration dating may be critical to device function and to protect the patient from device degradation through over-exposure to humidity, light or to temperature extremes. When such devices are opened-but-unused, hospitals and third-party reprocessors, unaware of potentially compromised product integrity, may ready the device for use in another patient.

One example of such a device is synthetic absorbable sutures. Because these sutures are designed to lose strength upon exposure to moisture or oxygen, they are hermetically sealed in packaging that controls the internal environment and protects the products from hydrolytic and oxidative degradation prior to use. Opened-but-unused sutures can be compromised through extended exposure to ambient temperature and humidity caused by: (1) improper packaging by the reprocessor, (2) long intervals between opening and reprocessing, (3) repeat exposure to elevated temperatures and humidity levels associated with sterilization, and (4) inappropriate repackaging techniques and materials. One company conducted detailed moisture, temperature and sterilization studies on its various suture products and found that:

- high-oxygen in packaging caused a significant reduction in *in vivo* tensile strength;
- high moisture content in packaging caused a significant reduction in *in vivo* tensile strength and significantly reduced shelf life;
- slight temperature variations from specification-levels in the sterilization process also significantly decreased *in vivo* tensile strength; and
- some sutures underwent significant degradation when cobalt radiation was used.

Similarly, a study conducted by scientists within the Center for Devices and Radiological Health's Office of Science and Technology (OST)[2] expressed concerns that

---

[2] "Effects of Repeated Ethylene Oxide Sterilization on Synthetic Absorbable Sutures," *Medical Device UserFacility Reporting,* Issue No. 38, Spring 2002.

reprocessors of sutures would not be aware of the sterilization protocol for a given suture type since that information is rarely contained on the package labeling; that re-sterilization destroyed the inner seal of some sutures, potentially exposing the sutures to humidity – a concern since hydrolysis was the primary mechanism for degradation in the tested sutures; and that re-sterilization caused different changes in suture strength, depending on suture type which can imply potential changes in *in vivo* degradation behavior.

Importantly, one of the OST study conclusions was that mechanical integrity issues caused by re-sterilization "could result in wound dehiscence or other complications."

Another example of a device that may be compromised through repeated sterilizations is stainless steel saw blades. It is at least one company's experience that their most aggressive saw blade showed a 10 percent decrease in cutting efficiency after two standard autoclave cycles.

In other cases, some single-use devices have coatings (e.g., coated stents) that can only go through one sterilization process and still maintain functionality. In this case, these opened-but-unused products would not be able to be re-sterilized.

FDA's policy regarding opened-but-unused, single-use devices should reflect that each device's original equipment manufacturer is in the best position to assess the effects of re-sterilization on its device and should therefore be consulted before any re-sterilization program is undertaken. Many OEMs will provide cleaning and sterilization instructions to hospitals that request them for specific opened-but-unused, single-use devices that can be safely re-sterilized. AdvaMed strongly objects to some comments already submitted to this docket that suggest that FDA should *require* original equipment manufacturers to prospectively provide re-sterilization instructions for opened-but-unused, single-use devices. Such statements fail to consider that certain single-use devices cannot be re-sterilized because of material integrity or other concerns noted above. Finally, providing such re-sterilization information can expose the OEMs to significant liability for encouraging the processing of its devices by someone other than themselves.

FDA should also consider whether hospitals and reprocessors can appropriately validate their sterilization processes and track the number of times a product has been opened-but-unused and re-sterilized. Hospital or sterilization conditions that are outside the parameters of those 99999set by the OEM may impact the sterility or performance of the device. Additionally, as noted above, in some cases, re-sterilization affects the mechanical integrity of the device. This could be compounded by repeated re-sterilizations. Thus, a tracking mechanism is required for some devices. These parameters should also consider sterilant residual levels so that patients and staff are not exposed to EO residuals that are above allowable limits. Finally, FDA should also consider the potential for contamination of open-but-unused, single-use

devices from airborne pathogens and whether hospital and reprocessor sterilization processes alone are sufficient, or if validated cleaning processes may also be needed.

We appreciate the opportunity to comment on this issue and look forward to working with FDA to revise its current policy.

Sincerely,

Tara Federici

Tara M. Federici
Associate Vice President
Technology and Regulatory Affairs